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EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	**PAPER NUMBER**
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,495	WALTER ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☒ Claim(s) *1-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/002,939.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are currently pending in the instant application. Claim 14 is withdrawn from consideration as being for non-elected subject matter and claims 1-13 are objected and rejected.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-13 and the further election of the compound (Z)-3-{1-[4-(piperidinomethyl)-phenylamino]-1-phenyl-methylidene}-5-ethylsulphonylamino-2-indolinone in the reply filed on 8 November 2005 is acknowledged.

Therefore, as stated on pages 3 and 4 or the restriction requirement upon the election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound and examination will then proceed on the elected compound and the scope of the determined independent invention encompassing the elected compound.

The elected invention for search and examination is the products of the formula (I) wherein:

X, **R1**, **R3**, **R5**, **R6** are as found in claim 1;

R2 is selected from the group consisting of

a C_{1-6} alkyl group optionally substituted by one or more halogen atoms;

a phenyl group or a C_{2-6}-alkenyl group optionally substituted by a phenyl group, wherein the phenyl moiety may be substituted in each case by a fluorine, chlorine, bromine or iodine atom, by a C_{1-3}-alkyl or C_{1-3}-alkoxy group;

a phenyl group which may be disubstituted by fluorine, chlorine, bromine or iodine atoms, by C_{1-3} alkyl or C_{1-3} alkoxy groups, wherein the substituents may be identical or different;

a phenyl group substituted by a trifluoromethyl, carboxy, C_{1-3}-alkoxycarbonyl, aminocarbonyl, cyano, aminomethyl, nitro or amino group; and

a C_{4-6}-alkyl, C_{3-7}-cycloalkyl, trimethylphenyl or naphthyl group,

R4 is a phenyl or naphthyl group substituted by R7, which may additionally be substituted by a chlorine or bromine atom or a nitro group; and

R7 is a C1-3-alkyl group which is substituted by a piperidino group which may be substituted by one or two C1-3 alkyl groups, which may in turn be terminally substituted by a hydroxyl, amino or C2-4alkanoylamino group, or by a C5-7 cycloalkyl or phenyl group and by a hydroxyl group and in the above mentioned piperidino group a methylene group adjacent to the nitrogen atom may be replaced by a carbonyl group.

The remaining subject matter of claims 1-13 that is not drawn to the above elected invention and the subject matter of claim 14 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining products which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected product and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the products of the formula (I) wherein R2 is a 5-membered heteroaromatic group or a 6-membered heteroaromatic group; R4 is not substituted by R7, additionally substituted by a 5-membered heteroaromatic group, or a 6-membered heteroaromatic group; and/or R7 is

a fluorine, chlorine, bromine, iodine, cyano, a methoxy group or a C2-3alkoxy group, a C2-4 alkylamino group, a C1-3 alkyl group which is substituted by a hydroxyl, carboxy, morpholino, thiomorpholino, 1-oxo-thiomorpholino, 1,1-dioxo-thiomorpholino, piperazino, a 5 to 7 membered cycloalkenyleneimino group, etc.

The above mentioned withdrawn products which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the products of the elected invention. The withdrawn products differ from those of the elected invention, such as, for example, by pyridine, piperazine, oxazolyl, imidazolyl, morpholine, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the products can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 544 subclass (358)+ piperazine, class 548 subclass (215)+ oxazolyl, class 548 subclass (356.1)+ imidazolyl, class 544 subclass (106)+ morpholine etc. Therefore, again, the products which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn products are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claim 12 is objected to because of the following informalities: There are commas missing between the recitation of some of the compound names which makes the claim difficult to comprehend, see for example page 105, lines 28 and 29, wherein the two compounds: (Z)-3-[1-(4-piperidinomethyl-phenylamino)-1-phenyl-methylidene-5-methylsulphonylamino-2-indolinone and (Z)-3-{1-[4-(piperidineomethyl)-phenylamino]-1-phenyl-methylidene}-5-ethylsulphonylamino-2-indolinone are not separated by any type of punctuation. It is suggested that applicant provide commas between each compound named in claim 12. Appropriate correction is required.

Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. For example, multiple dependent claim 13 is dependent on multiple dependent claims 8 and 10 and their dependent claims 9 and 11. See MPEP § 608.01(n).

Claims 1-13 are objected to as containing non-elected subject matter. Specifically, the non-elected subject matter present in claims 1-13 is the subject matter other than that as presented supra as the elected invention for search and examination. Claims 1-13 presented drawn solely to the elected invention identified supra would overcome this objection as the claims would then be drawn solely to the elected invention for search and examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied

with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

This application claims benefit to a provisional application No. 60/251,055 filed on 12/01/2000 in a language other than English. Applications that claim benefit of a provisional application filed in a non-English language must include an English translation of the non-English language provisional application and a statement that the translation is accurate unless the translation and the statement were previously filed in the provisional application. See 37 CFR 1.78(a)(5). The English translation of the non-English language provisional application and the statement that the translation is accurate as required by 37 CFR 1.78(a)(5) is missing, i.e. it is not found in the instant application or in the provisional application No. 60/251,055. Applicant must supply the missing translation and statement in the reply to this Office action prior to the expiration of the time period set in this Office action.

Accordingly, the date of 11/01/2001, the filing date or US Patent Application 10/002,939, to which applicant properly claims priority under 35 USC 120, is relied upon for prior art purposes. Furthermore, the 35 USC 102(a) and 103(a) rejection below cannot be overcome by the foreign priority papers because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "or" between the definition of R4 and R5 of claim 1, page 96 line 18, renders the claims indefinite. The term "or" renders the claims indefinite because the claims only define the values of X, R1, R2, R3 and R4 "or" the values of R5, R6 and R7, but does not define all the variables at once. Therefore, for example, when X, R1, R2, R3 and R4 are as defined in the claims, it is unclear what the values of R5, R6 and R7 are as they are only defined in the alternative to the definitions of X, R1, R2, R3 and R4 and vice-versa. It is suggested that applicant delete the term "or" from line 18, page 96.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of copending Application No. 10/646,423, respectively. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Specifically, applicants' instant claims 1-13 are identical to claims 1-13 of copending Application NO. 10/646,423. See for example, applicants' instant claim 2 and 3:

2. A compound of formula I according to claim 1 wherein the sulphonylamino group of the formula R_2-SO_2NR_6- is linked to the 5-position of the indolinone group.

3. A compound of formula I according to claim 1, wherein:

R_3 is a phenyl group optionally substituted by a fluorine, chlorine or bromine atom, by a C_{1-3}-alkyl, hydroxy, C_{1-3}-alkoxy, C_{1-3}-alkylsulphenyl, C_{1-3}-alkylsulphinyl, C_{1-3}-alkylsulphonyl, phenylsulphenyl, phenylsulphinyl, phenylsulphonyl, nitro, amino, C_{1-3}-alkylamino, di-(C_{1-3}-alkyl)-amino, C_{2-5}-alkanoylamino or N-(C_{1-3}-alkylamino)-C_{2-5}-alkanoylamino group.

compared to copending Application No. 10/646,423 conflicting claims 2 and 3:

2. **A compound of formula I according to claim 1 wherein the sulphonylamino group of the formula R_2-SO_2NR_6- is linked to the 5-position of the indolinone group.**

3. **A compound of formula I according to claim 1, wherein:**

R_3 is a phenyl group optionally substituted by a fluorine, chlorine or bromine atom, by a C_{1-3}-alkyl, hydroxy, C_{1-3}-alkoxy, C_{1-3}-alkylsulphenyl, C_{1-3}-alkylsulphinyl, C_{1-3}-alkylsulphonyl, phenylsulphenyl, phenylsulphinyl, phenylsulphonyl, nitro, amino, C_{1-3}-alkylamino, di-(C_{1-3}-alkyl)-amino, C_{2-5}-alkanoylamino or N-(C_{1-3}-alkylamino)-C_{2-5}-alkanoylamino group.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 8 of U.S. Patent No. 6,794,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because: conflicting claims 1-4 and 8 of US Patent No. 6,794,395 claim a compound of the formula (I), in conflicting claim 1 wherein X can be oxygen; R1 an be a C1-3alkylsulphonylamino or phenylsuophonylamino; R2 can be a hydrogen; R3 is a phenyl; R4 can be a hydrogen; R5 can be a hydrogen; and R6 can be a C1-4alkyl terminally substituted by a 4-to 7-membered cycloalkyleneimino group wherein one or two hydrogen atoms is optionally replaced by a C1-3alkyl group. Conflicting claim 8 claims a pharmaceutical composition of the compound of claim 1. Preferences are seen in conflicting claims 2-4, such as wherein X is oxygen; R4 is hydrogen, R5 is hydrogen; R1 can be an amino substituted by C1-3alkylsulphonyl and phenylsulphonyl; and R6 can be a C1-3alkyl terminally substituted by piperidino which may additionally be substituted by one or two C1-3alkyl groups (conflicting claim 2). Further preferences

are found in conflicting claim 3 wherein X is oxygen; R4 and R5 are hydrogen; R1 can be an amino group substituted with methanesulphonyl or benzenesulphonyl; and R6 can be a C1-3alkyl terminally substituted by a piperidino group optionally substituted by one or two methyl groups. Conflicting claim 4 specifies R2 as hydrogen. Furthermore, compounds (3) and (4), found on columns 36 and 37 of the conflicting patent, are:(3) 6-methanesulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone ,and (4) 6-benzenelsulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone,
which provide support for the conflicting claims in the conflicting patent.

The difference between applicants' instant claims 1, 3-11 and 13 and the conflicting claims 1-4 and 8 is that the conflicting claims of US Patent No. 6,794,395 overlap with applicants' instantly claimed invention and provide preferences towards applicants instantly claimed invention which corresponds to the conflicting invention wherein X is oxygen; R1 can be an alkylsulphonylamino or phenylsulphonylamino; R2 is hydrogen; R3 is phenyl; R4 and R5 are hydrogen; and R6 can be a C1-3alkyl substituted by a piperidino group optionally substituted by one or two methyl groups. The difference between applicants' instant claims 2 and 12 and the conflicting claims 1-4 and 8 is that the conflicting claims of US Patent No. 6,794,395 claims preferred compounds which are positional isomers of applicants' claims, i.e. on position 6 of the indolinone group instead of position 5.

However, applicants' instantly claimed invention of claims 1-13 is considered obvious type double patenting over conflicting claims 1-4 and 8 of US Patent No.

6,794,395 as one of ordinary skill at the time of the invention when faced with the conflicting claims would have been motivated to prepare additional compounds useful for the treatment of, for example, rheumatoid arthritis as the conflicting claims either provide preferences towards compounds which are positional isomers of the claims or as the conflicting claims overlap with the instantly claimed invention and provide preferences towards compounds wherein R1 is an alkylsulphonylamino or phenylsulphonylamino and R6 is a C1-3alkyl substituted by a piperidino group optionally substituted by one or two methyl groups. The motivation would be to prepare additional compounds useful for the treatment of rheumatoid arthritis and since nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by US Patent No. 6,794,395, since such structurally related compounds suggest one another and would be expected to share common properties.

Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of copending Application No. 10/640,926. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of copending Application No. 10/640,926 discloses a pharmaceutical composition comprising, for example the compounds of:

(A) (Z)-3-(1-(4-(piperidin-1-yl-methyl)-phenylamino)-1-phenyl-methylene)-5-(methylsulfonylamino)-2-indolinone;

(B) (Z)-3-(1-(4-(piperidin-1-yl-methyl)-phenylamino)-1-phenyl-methylene)-5-(ethylsulfonylamino)-2-indolinone;

(D) (Z)-3-(1-(4-(piperidin-1-yl-methyl)-phenylamino)-1-phenyl-methylene)-5-(phenylsulfonylamino)-2-indolinone;

(E) (Z)-3-(1-(4-(piperidin-1-yl-methyl)-phenylamino)-1-phenyl-methylene)-5-(4-amino-phenylsulfonylamino)-2-indolinone; and

(G) (Z)-3-(1-(4-(4-(3-aminopropyl-piperidin-1-yl-methyl)-phenylamino)-1-phenyl-methylene)-5-(ethylsulfonylamino)-2-indolinone; and

(b) one or more other drugs selected from NSAIDs, steroids, DMARDs, immunsuppressives, biologic response modifiers and antinfectives.

. Conflicting claim 12, which depends from conflicting claim 11, specifies that the pharmaceutical composition additionally comprises an additional pharmaceutical acceptable carrier and/or diluent. Therefore, conflicting claim 12, which discloses a pharmaceutical composition comprising a compound (A), (B), (D), (E), (G) an additional drug (b) and a pharmaceutical acceptable carrier and/or diluent, anticipates applicants' instant claim 13, which claims a pharmaceutical preparation comprising a compound according to claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 and a pharmaceutically acceptable carrier, as conflicting claim 12 comprises within its pharmaceutical composition, specific compounds within applicants instant elected invention of formula (I) and a pharmaceutically acceptable carrier and/or diluent. Conflicting claims 13-20 further define the additional drug (b) of claim 11. As conflicting claim 12 anticipates applicants' instant claim 13 it therefore renders applicants' claim 13 as rejected under obvious type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-8, 10 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/16130. *(Note: page numbers are also provided for the English language equivalent, US Patent No. 6,794,395)*

WO 01/16130 discloses the compounds (3) and (4) on page 74 (columns 36 and 37 of US Patent No. 6,794,395) which are:

(3) 6-methanesulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone and

(4) 6-benzenelsulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone

These compounds correspond to applicants instant elected invention wherein: the R2-SO2NR6 group is linked to the 6-position of the indolinone group; R2 is C1-6alkyl (3) or phenyl group (4); R6 is hydrogen; R1 is hydrogen; X is oxygen; R3 is a phenyl group; R5 is hydrogen; R4 is a phenyl substituted in the 4 position by R7; and R7 is C1-3alkyl substituted with piperidino group.

WO 01/16130 also discloses pharmaceutical compositions in examples 12-18, pages 104-108 (US Patent No. 6,794,395, columns 50-52).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Specifically, a translation of DE 100 54 019 is not found in either this application or the parent application 10/002939.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/16130. *(Note: page numbers are also provided for the English language equivalent, US Patent No. 6,794,395)*

Determining the scope and contents of the prior art

WO 01/16130 discloses the products of the formula (I), page 1 (US column 1), wherein R6 can be a C1-4alkyl group, which may be terminally substituted by a 4-7 membered cycloalkyleneimino group wherein one or two hydrogen atoms may each be replaed by a C1-3alkyl group, page 7 (US column 4). Pages 12-13 (US column 6) disclose preferred compounds wherein X can be oxygen, R1 can be an amino substituted byC1-3-alkylsulphonyl, R2 can be hydrogen, R3 can be phenyl, R4 is hydrogen, R5 is hydrogen and R6 can be a C1-3alkyl group which may be terminally substituted by a piperidino whilst the piperidino group may additionally be substituted by one or two C1-3 alkyl groups. Particularly preferred compounds are disclosed on pages 15 and 16 (US column 7) wherein X is an oxygen atom, R1 can be an amino group substituted by methanesulphonyl or benzolsulphonyl, R2 can be hydrogen, R3 can be a phenyl, R4 is a hydrogen, R4 is a hydrogen and R6 can be a C1-3alkyl group which may be terminally substituted by a piperidino group optionally substituted by one or two methyl groups. WO 01/16130 discloses the compounds (3) and (4) on page 74 (columns 36 and 37 of US Patent No. 6,794,395) which are:

(3) 6-methanesulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone and

(4) 6-benzenelsulfonylamino-3-(Z)-{1-[4-(piperidin-1-yl-methyl)-anilino]-1-phenyl-methylidene}-2-indolinone.

WO 01/16130 also discloses pharmaceutical compositions in examples 12-18, pages 104-108 (US Patent No. 6,794,395, columns 50-52) and discloses that the

compounds are useful, for example, for the treatment of rheumatoid arthritis on page 35 (US column 16).

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and applicants' instant claims 9 and 11 is that the prior art generically encompasses compounds wherein R7 is 2,6-dimethylpiperidino)-methyl and provides preferences towards compounds wherein R7 is 2,6-dimethylpiperidino)-methyl but fails to prepare a specific species wherein R7 is 2,6-dimethylpiperidino)-methyl. The compounds of (3) and (4) differ by failing to have the 2 methyl substituents on the piperidino group.

The difference between the prior art and applicants' instant claims 2 and 12 is that the prior art prepares the compounds (3) and (4) which are positional isomers of the compounds of applicants' claim 2 and 12, i.e. the R2SO2NR6 is linked to the 6-position of the indolinone group instead of the 5-position, see applicants' compound (Z)-3-[1-(4-piperidinomethyl-phenylamino)-1-phenyl-methylidene]-5-methylsulphonylamino-2-indolinone (claim 12, page 105, lines 28-29)

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds of applicants' instant claims 9 and 11 wherein R7 is 2,6-dimethylpiperidino)-methyl when faced with WO 01/16130 as the prior art compounds generically encompass applicants' instantly claimed product wherein R7 is 2,6-dimethylpiperidino)-methyl and the prior art reference provides multiple preferences towards the position equivalent to applicants'

R7 as a C1-3alkyl group terminally substituted by a piperidino group substituted by one or two methyl groups. The motivation would be to prepare additional compounds useful for the treatment of rheumatoid arthritis.

In regards to applicants' claims 2 and 12, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare compounds of applicants' instant claims 2 and 12 wherein the R2-SO2NR6 group is linked to the 5-position of the indolinone group since the prior art prepares compounds, such as (3) and (4) which are positional isomers of applicants' instant claims, i.e. the R2-SO2NR6 group is linked to the 5-position of the indolinone group. The motivation would be to prepare additional compounds useful for the treatment of rheumatoid arthritis since nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by WO 0116130 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Specifically, a translation of DE 100 54 019 is not found in either this application or the parent application 10/002939.

Conclusion

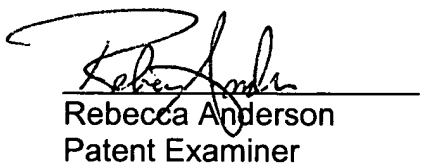
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571)

272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



January 25, 2006

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